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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,185	03/07/2001	Jochen G. Salfeld	BBI-043CPUSCN	1672

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	17

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
801,185	SALFELD et al.
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 3/17/03.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 74-121 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☑ Claim(s) 74-121 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ Th proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*C rtified copies not received:_____.

Attachm nt(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Oth r_____

Office Action Summary

The amendment of 3/17/03 has been entered. Claims 74-121 are pending and under examination.

Claims 101 and 120 are objected to because of the following informalities: these claims conclude without a period. Appropriate correction is required.

Claims 83-84, 88-98, 103 and 105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Markush group of claim 83 is improper by virtue of containing a twice recited member --i.e. "Intravenous immune globulin" and "intravenous immunoglobulin". In claim 83 "thalidomide related drugs" is unclear, because no structural or activity relatedness is stated.

In claim 83 "orally administered peptides" is unclear because these have no structural or functional limitations.

Regarding claim 83, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as"

and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 83 recites the broad recitation chelates, and the claim also recites "including diethylenetrizmine pentaacetic acid" which is the narrower statement of the range/limitation.

The rejections applied above to claim 83 are also applicable to claims 88, 90, 96, 103, 105 and 111, to the extent that the improper terms are recited in each.

Claim 84 is incomplete at its last line and also fails to end with a period. All claims depending from 84 are also rejected.

Claims 83, 88, 90, 103 and 105 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter.

Specifically each claim recites "collagen" as a Markush group member. What the specification teaches at page 31, line 3 is orally administered collagen, not mere collagen. Because the claimed composition would encompass collagen in forms other than what is orally

administered and because the claimed method would encompass routes of administration other than oral, applicant is claiming more broadly than can be supported by the original disclosure.

Claims 88 and 103 contain new matter because they are not limited to treatment of a particular disease recited in the original disclosure. The laundry list of agents recited appears to have been gleaned from particular diseases (rheumatoid arthritis, etc.), each followed by a list of agents particularly appropriate for the recited disease. By not limiting the treatment method to a particular disease (e.g. as in claims 90, 92, 94, 96, 98, 105, 107, 109, 111 and 113) applicant is claiming beyond what is described.

Claims 83, 88, 90, 103 and 105 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's original disclosure has not properly described the subgenus of agents that is constituted by "orally administered peptides".

Applicant has given no structural or functional description of what the peptide agents are or what they are intended accomplish. Since the number of compounds falling within the subgenus of "peptides" is vast and since different peptides will vary widely in their functional activities, one has no idea as to what the subgenus encompasses. Note that one skill could envision the function of an agent such as "anti-IL-12 antibodies" and one would know how to prepare such. Likewise one of skill would know how to screen for an agent such as an "ICE

inhibitor". Likewise one of skill could go to the Merck Index or the Physicians Desk Reference and obtain the structure of an agent such as indomethacin. ON the other hand, how would one know how to screen for appropriate "peptides", absent a disclosure of what functional activity is intended? Where would one find "peptides" as an entry in the Merck Index or Physician's desk reference?

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 24-25 and 28 of U.S. Patent No. 6,090,382. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 74 is essentially the same as issued claim 1, with the limitations of issued claims 24-25 incorporated therein, except for the fact that instant claim 74 additionally recites a genus of disorders to be treated.

Nevertheless, the instant and issued claims clearly encompass common subject matter, and a disclaimer is required in order to assure that any patent that presently issues would remain commonly assigned with the issued patent.

Claims 74 and 83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 24-25 of U.S. Patent No. 6,090,382 in view of Aggarwal et al. (5,795,967). Claim 74 has been discussed supra.

Aggarwal et al. teach the further feature of naming agents which can be used in conjunction with an anti-TNF alpha antibody for treatment of inflammatory conditions. At col. 7, line 66 - col. 8, line 6 they teach agents recited in instant claim 83. Thus claim 83 offers no patentable distinction.

Claims 84-87, 89, 91, 93, 95, 97, 99-102, 104, 106, 108, 110 and 112 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 15, 17, 22, 36-39, 69, 87 and 93 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because

instant claims 84-87 parallel issued claims 4-7. Likewise instant claims 99-102 parallel issued claims 36-39. The only difference is that the instant claims require the administrating of "one additional therapeutic agent"; this additional feature is shown in issued claim 69.

The diseases recited in instant claims 89, 91, 93, 95, 97, 104, 106, 108, 110 and 112 are taught in issued claims 15, 17, 22, 87 and 93.

The instant claims are thus not patentably distinct from those issued in Pat '015; a disclaimer is required to assure that any patent that presently issues would remain commonly assigned with the issued patent.

Claims 84-91, 93-97, 99-106 and 108-112 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 15, 17, 22, 36-39, 87 and 93 of U.S. Patent No. 6,509,015 in view of Aggarwal et al. Instant claims 84-87 parallel issued claims 1-4. Likewise instant claims 99-102 parallel issued claims 36-39. The only difference is that the instant claims require the administering of "one additional therapeutic agent".

Aggarwal et al. show that administration of an additional therapeutic agent, along with an antibody to TNF alpha was art known. See col. 7, line 66 - col. 8, line 6. Therein Aggarwal et al. teach agents recited in instant claims 88, 90, 94, 96, 103, 105, 109 and 111.

The diseases instantly recited in instant claims 89, 91, 93, 95, 97, 104, 106, 108, 110 and 112 (rheumatoid arthritis, multiple sclerosis, sepsis, IBD) are taught in claims 15, 17, 22, 87 and 93 of applicant's '015 patent.

From the above, it is clear that the instantly recited disease states to be treated and the instantly recited additional therapeutic agents provide no patentable distinction.

Claims 84-87, 92, 98-102, 107 and 113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 36-39 and 69 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant clams 84-87 and 99-102 have been considered supra with respect to the listed claims of Pat. '015.

The particular therapeutic agents recited in instant claims 92, 98, 107 and 113 are not recited in any of the claims of Pat. '015, nor are these reagents taught in any cited secondary reference. However, since these are taught in the specification Pat '015, their use in a method of treatment would be encompassed by issued claim 69 and its dependents. A disclaimer is required since applicant could have recited treatment methods using these agents when drafting the claims of the '015 Pat.

Claims 114-121 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 14-121 parallel issued claims 4-7 and 36-39. The only difference is that the instant claims recite a Markush group of particular disorders.

These disorders are not taught in the issued claims or in any secondary reference. However, since these are taught in the specification of Pat '015, their treatment is encompassed

by the issued claims. Since applicant could have earlier recited these disorders in the issued claims, a disclaimer is required.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

May 28, 2003

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644